

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of
ECUMED HEALTH GROUP
a corporation,

and

AMADOR REYES,
JUAN C. CARRAI,
RICHARD W. STONE, M.D., and
ERLINDA E. ENRIQUEZ, M.D.,
individuals.

ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY

FDA Docket: 2004H-0322

COMPLAINANT'S REQUEST FOR PRODUCTION OF DOCUMENTS

Pursuant to 21 C.F.R. § 17.23, Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration ("FDA"), requests that Respondents, within 30 days after service of this request, produce for inspection and copying at the offices of the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland, 20857, the documents requested herein.

DEFINITIONS AND INSTRUCTIONS

As used herein,

1. "Respondents" means Ecumed Health Group ("Ecumed"), Amador Reyes, Juan C. Carrai, Richard W. Stone, M.D., and Erlinda E. Enriquez, M.D., and any person acting on behalf of them,

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including, but not limited to, employees and independent contractors.

2. "You" and "your" refers to Respondents.
3. "Person" means any individual, partnership, corporation, association, trust, store, franchise, sole proprietorship, or other legal or business entity.
4. "Documents" is defined in 21 C.F.R. § 17.23.
5. "Communication" means the transmittal of information from one person to another person or persons whether written or oral, including, but not limited to, telephone conversations, meetings, letters, telexes, facsimiles, electronic messages and email, and all other documents relating to such communications.
6. "Receipts" is defined in 13 C.F.R. § 121.104.
7. The terms "relating to" and "regarding" mean that which constitutes, comprises, contains, consists of, sets forth, proposes, shows, discloses, describes, discusses, explains, summarizes, concerns, reflects, authorizes, or refers to, directly or indirectly.
8. Use of the singular shall be deemed to include the plural and use of the masculine shall be deemed to include the feminine, as appropriate, and vice versa. As used herein, the terms "and" and "or" should be interpreted liberally, as conjunctive, disjunctive, or both depending on the

context, so that the fullest disclosure of information is achieved.

9. These document requests are intended to be continuing in nature so as to require supplemental or amended responses or productions by Respondents. Such supplemental or amended answers should be furnished within ten days of the date on which the additional information is obtained.
10. If you withhold from disclosure any requested documents on the basis of any asserted privilege, including the attorney-client privilege and the work product doctrine, state the nature of the privilege or protection claimed and the basis for the claim as to each specific document request. Each document and all information claimed as privileged shall be unambiguously described by setting forth at least:
 - a. the identity of all persons who initiated, received, or were privy to such information, communications, or documents;
 - b. whether any such persons were counsel to you and were acting in such capacity, and if so, which ones;
 - c. the date of such information, communication, or document;
 - d. its subject matter; and

- e. a concise statement of the reasons for the assertion of privilege as to such information, communication, or document.
- 11. If you object to any part of a document request, set forth the basis for your objection and respond to all parts of the document request to which you do not object.
- 12. If you believe there to be an ambiguity in construing a document request, definition, or instruction, set forth the matter you find ambiguous and the construction selected in responding to the documents requests.

DOCUMENT REQUESTS

Please produce the following:

- 1. All documents relating to: (i) all official corporate acts, including, but not limited to, corporate formation and dissolution, shareholders' meetings, directors' meetings, and corporate resolutions; (ii) the composition of the corporation, its management, owners, and employees, including lists of directors, officers, and shareholders; and (iii) all audited financial statements of:
 - a. Respondents;
 - b. Any person employing, using, or conducting business or operating under, or that has employed, used, conducted business or operated under, the name Ecumed Health Group;

- c. Any predecessor or successor, parent or subsidiary, of Ecumed Health Group;
 - d. Any other person, in which any of the Respondents, and/or any immediate family member of any of the Respondents, and/or any predecessor or successor, parent or subsidiary, of Respondents, individually or collectively, held ten percent or more of the ownership interests.
- 2. All documents relating to income tax returns for years 2001, 2002, and 2003 for each of the Respondents.
- 3. All documents reflecting any and all the assets, including any ownership interests in any business entity, of each of the Respondents and any of their immediate family members.
- 4. All documents relating to all financial transactions between Respondents, including all contracts, or other indicia of employment or ownership relationships, and all records of payments.
- 5. All documents relating to the annual receipts and number of employees of:
 - a. Respondents;
 - b. Any person employing, using, or conducting business or operating under, or that has employed, used, conducted business or operated under, the name Ecumed Health Group.

- c. Any predecessor or successor, parent or subsidiary, of Ecumed Health Group;
 - d. Any affiliate, as that term is used in 13 C.F.R. § 121.103, of any Respondent, including, but not limited to: (i) any person in which any Respondent has the power to control; (ii) any person in which any Respondent is an officer, director, or partner, or is otherwise able to control the board of directors or management of such person; (iii) any person that controls or has the power to control any Respondent; and (iv) any other person, in which any of the Respondents, and/or any immediate family member of any of the Respondents, hold fifty percent or more of the ownership interests.
- 6. All documents relating to the identity and duties of the person(s) responsible for the operations of Ecumed on a day-to-day basis.
 - 7. All documents relating to the identity and duties of the person(s) responsible for conducting mammography examinations and procedures, and ensuring mammography quality and compliance with the Mammography Quality Standards Act of 1992, 42 U.S.C. § 263b, on a day-to-day basis at Ecumed.

8. All documents relating to the duties, responsibilities, employment, and supervision of Amador Reyes, Juan Carrai, Richard Stone, Erlinda Enriquez, and Janet Labrada.
9. All documents relating to communications among Amador Reyes, Juan Carrai, Richard Stone, Erlinda Enriquez, and/or Janet Labrada concerning mammography certification, the American College of Radiology, and FDA.
10. All documents relating to the mammography training given by Judy Sorge, RT, on June 8, 2002.
11. Any and all documents relating to any communications between any of the Respondents and Complainant, and any of the Respondents and the American College of Radiology, including, but not limited to, logs, journal entries, telephone records, and receipts of delivery.
12. All documents relating to any certificates and/or accreditation received by Respondents from FDA, the American College of Radiology, or any other entity.
13. All documents reflecting the identities and locations of each facility, as defined in 42 U.S.C. § 263b(a)(3), that is owned or operated by, or that employs, directly or indirectly, any Respondent, or that conducts business or operates under the name Ecumed Health Group.
14. All documents relating to Erlinda Enriquez' alleged defense in paragraph 1 of the "Defenses" Section of Dr. Enriquez's

Answer, which alleges that she "was neither an owner or principal of Ecumed Health Services, Inc."

15. All documents relating in any way to Erlinda Enriquez' alleged defense in paragraph 3 of the "Exceptions to the Requested Penalty" Section of her Answer, which she alleges that she learned that Juan Carrai interpreted films on his own, forged Dr. Enriquez' signature, admitted responsibility for such actions, and resigned from Ecumed.
16. All documents relating to the alleged defense of Richard Stone in the first unnumbered paragraph of the "Defenses" Section of his Answer, which alleges that he was "hired by [Ecumed] on an independent contractor basis to review mammography films."
17. All documents relating to the alleged defense of Ecumed Health Group and Amador Reyes in paragraph 4 of the "Affirmative Defenses" Section of their Answer submitted on September 17, 2004 (entitled "Motion For Enlargement of Time"), which alleges that Ecumed Health Group and Amador Reyes have "no ability to pay the requested penalty."
18. All documents relating to Juan Carrai's alleged defense in paragraph 4 of the "Affirmative Defenses" Section of his Answer, which alleges that Mr. Carrai "has no ability to pay the requested penalty."

19. All documents that Respondents have obtained in their investigation into Complainant's allegations.
20. All documents that you may introduce into evidence in connection with the hearing or any dispositive motions in this matter.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Michael N. Varrone", is written over a horizontal line.

Michael N. Varrone
Attorney for Complainant
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Radiological Health
United States Food and Drug
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CERTIFICATE OF SERVICE

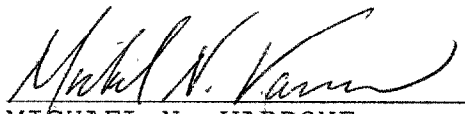
I certify under the penalty of perjury that on this 18th day of February, 2005, I have caused a copy of the foregoing Complainant's Request for Production of Documents to be served by facsimile and overnight mail on the following:

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